

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Raymond P. Feith et al.

Application No.: 10/816,183

Confirmation No.: 7854

Filed: March 31, 2004

Art Unit: 3763

For: MULTI-VALVE INJECTION/ASPIRATION
MANIFOLD WITH NEEDLELESS ACCESS
CONNECTION

Examiner: Q. H. Vu

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

As required under 37 C.F.R. § 41.37(a), this brief is filed within the two month extension of time period of the Panel Decision issued in this case on November 20, 2009.

The fees required under 37 C.F.R. § 41.20(b)(2) are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

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| I. | Real Party In Interest |
| II | Related Appeals and Interferences |
| III. | Status of Claims |
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| V. | Summary of Claimed Subject Matter |
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I. REAL PARTY IN INTEREST

The real party in interest for this appeal is: Medegen, Inc., a California corporation.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 3 claims pending in application.

B. Current Status of Claims

1. Claims canceled: 4-6, 9-19 and 22-23
2. Claims withdrawn from consideration but not canceled: 7-8, and 20-21
3. Claims pending: 1-3
4. Claims allowed: None
5. Claims rejected: 1-3

C. Claims On Appeal

The claims on appeal are claims 1-3.

IV. STATUS OF AMENDMENTS

Applicant did not file an Amendment After Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The following provides a concise explanation of the subject matter defined in each independent claim involved in the Appeal, referring to the specification by page and line

number and to the drawings by reference characters, as required by 37 C.F.R.

§ 41.37(c)(1)(v). Each element of the claims is identified by a corresponding reference to the specification and drawings where applicable. However, the citation to passages in the specification and drawings are made by way of example only for the convenience of the Board, and does not imply that the limitations from the specification and drawings should be read into the corresponding claim element. Reference is made to the paragraph numbers shown in U.S. Patent Application Publication No. 2004/0243069.

According to independent claim 1, the subject matter is an injection port adapted for use with an intravenous line (Paragraph [0053], element 23, Figure 2). The injection port includes a housing defining a flow channel (Paragraph [0003], element 27, Figure 12) and having an injection lumen extending in fluid communication with the flow channel (Paragraph [0055], elements, 56, 58, 61, Figures 3 and 4), first portions of the housing defining a first valve seat (Paragraph [0061], element 96, Figure 12) around the injection lumen, second portions of the housing defining a second valve seat (Paragraph [0061], element 98, Figure 12) around the injection lumen, a valve element disposed to extend transverse to the injection lumen (Paragraph [0061], element 70, Figure 12), the valve element forming a first seal with the first valve seat in response to a first pressure, the first pressure resulting from fluid in the flow channel (Paragraphs [0016], [0019] and [0061], Figures 12 and 13), the valve element forming a second seal with the second valve seat in response to a second pressure, the second pressure resulting from fluid in the flow channel, the second pressure greater than the first pressure of the fluid in the flow channel (Paragraphs [0016], [0019] and [0062], Figures 12 and 13), and the valve element forming an open configuration between said lumen and said flow channel in response to a third pressure resulting from fluid in the injection lumen the third pressure greater than one of said first pressure and said second pressure (Paragraphs [0016], [0019] and [0064], Figure 19).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claim 1 is rejected under 35 U.S.C. § 112, first paragraph.

B. Claim 1 is rejected under 35 U.S.C. § 102(b) as anticipated by US 4,946,448 (hereinafter, *Richmond*).

C. Claims 1-3 are rejected under 35 U.S.C. § 103(a) as unpatentable over US 4,922,954 (hereinafter, *Blomquist*) in view of US 3,889,710 (hereinafter, *Brost*).

D. Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting over claims 1, and 5-7 of US 6,364,861 (hereinafter, the '*861 patent*').

VII. ARGUMENT

Appellant respectfully traverses the outstanding rejections of the pending claims, and requests that the Board reverse the rejections in light of the remarks contained herein. The claims do not stand or fall together. Instead, Appellant presents separate arguments for various independent and dependent claims. Each of these arguments are separated below and presented with separate headings and sub-heading as required by 37 C.F.R. § 41.37(c)(1)(vii).

A. 35 U.S.C. § 112 Rejection

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Appellee asserts that the specification does not support the amendments to claim 1 made in the preliminary amendment accompanying the RCE filed on February 24, 2009, wherein the Appellant amended claim 1 to recite that the first pressure results from fluid in the flow channel, the second pressure results from fluid in the flow channel, and the third pressure results from fluid in the injection lumen. Appellant respectfully traverses the rejection under 35 U.S.C. § 112, first paragraph. The amendments did not change the operation of the port of claim 1, but rather merely clarified the existing limitations of claim 1. As mere clarification, they could not fail to comply with the written description requirement as the unamended claim 1 was filed in the original specification.

Further, the limitations themselves contain ample support in the specification. The specification is clear that the invention concerns ports and manifolds for injecting fluids in IV lines. Page 1, lines 12-13 and 18-24. The operation of the port and first and second is illustrated by Figures 12 and 13 and described on pages 12 and 13 of the specification. Specifically, page 12, lines 24-31 describe the operation of the two seat valve of claim 1 and Figure 12 shows the position of the valve element 70 under normal fluid flow in the channel

resting against first valve seat 96. Page 12, lines 10-22 describe that in its normal configuration valve element 70 forms a seal with the first valve seat 96.

Next, with respect to the second pressure, when an injectate is introduced through an adjacent port a high pressure situation occurs in flow channel 49. The pressure, higher than the normal pressure in the flow channel, will cause the valve element to contact the second valve seat 98 as shown in Figure 13 and described on page 12, lines 24-31. With respect to the claimed limitation of the third pressure, page 13, lines 20-25 describe the operation of the port in this state, which is also shown by Figures 15 and 19. The specification is clear that under the fluid pressure of an injectate the valve element is bent downwardly and the injectate flows through the first valve and into the flow channel. Page 13, lines 20-25. This operation of the valve element can only occur if the pressure of the injectate is greater than the existing pressure in the flow channel, i.e., the first pressure or the second pressure.

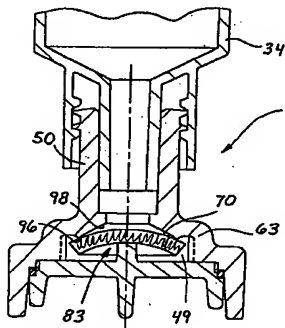


Figure 12

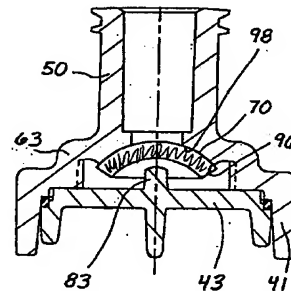


Figure 13

As the claim limitations used by the Appellee in supporting the rejection under 35 U.S.C. § 112, first paragraph are clearly supported by the written description for the reasons set forth above, the rejection under 35 U.S.C. § 112, first paragraph is improper and should be reversed.

B. 35 U.S.C. § 102(b) Rejection (*Richmond*)

Claim 1 is rejected under 35 U.S.C. § 102(b) as anticipated by *Richmond*.

Claim 1 requires a valve element that forms a first seal with the first valve seat in response to a first pressure, the first pressure resulting from fluid in the flow channel, the

valve element forming a second seal with the second valve seat in response to a second pressure, the second pressure resulting from fluid in the flow channel, the second pressure greater than the first pressure of the fluid in the flow channel, and the valve element forming an open configuration between said lumen and said flow channel in response to a third pressure resulting from fluid in the injection lumen the third pressure greater than one of said first pressure and said second pressure. Appellee asserts that *Richmond* describes these limitations, Appellant respectfully disagrees with the Appellee's characterization of *Richmond*.

In the Appellee's rejection in the office action dated April 30, 2009 (the "Office Action"), the Appellee correctly describes the operation of the check valve of *Richmond* in forming a seal using valve seat 78 in response to a pressure resulting from fluid in conduit 34. This pressure is represented by P1 in Figure 2.

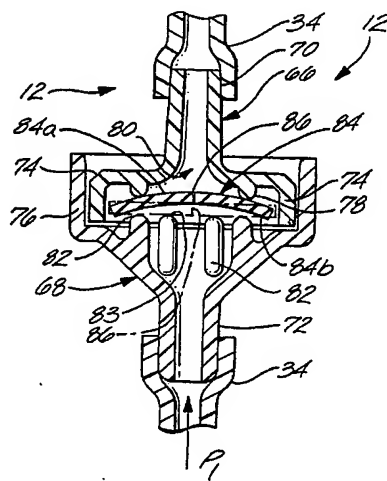


Figure 2 of *Richmond*

With respect to the second pressure and second seal recited in claim 1, the Appellee states that it is inherent that a second pressure (a force to press down) is greater than the first pressure, therefore the valve disk 84 is open and liquid flows downwardly. Appellant agrees with this description of *Richmond*, however, this is clearly different than the recitation of the second pressure in claim 1. Claim 1 requires both that the second pressure and the first pressure both result from fluid in the flow channel. The recitation of the Appellee describes the opposite. Further, the second pressure in claim 1 results in the formation of a second seal.

The Appellee's rejection admits that the pressure described in *Richmond* would cause the valve into an open position allowing liquid to flow.

The Appellee has also pointed to elements 82 and 83 as forming a second valve seat. This is contrary to the express teachings of *Richmond*. *Richmond* describes element 82 as a series of prongs, and element 83 as the rounded tips of those prongs that support the valve disk 84 when the valve is in its open positions. Column 4, lines 45-49. As is expressly stated in *Richmond*, the prongs are not a valve seat as described by the Appellee, but instead are used to support the valve disc 84 when the check valve is in the open conditions, permitting liquid to flow. Column 4, lines 52-55. *Richmond* states specifically that when the disc (valve) is in the open condition, as shown by the dashed lines in Figure 2, "liquid flows downwardly through the line 34, through the check valve upper housing 66, between the edge of the valve disc 84 and the interior of the skirt 74, through the spaces between projections 82, out through the lower housing, and into the downstream portion of the system." Column 4, lines 55-62. Prongs 82 are, therefore, not a valve seat upon which the valve element can form a second seal in response to the second pressure as required by claim 1.

While *Richmond* describes a check valve with a closed position in response to a downstream pressure and an open position in response to an upstream pressure, nowhere does *Richmond* describe the valve element forming a second seal with the second valve seat in response to a second pressure, the second pressure resulting from fluid in the flow channel, the second pressure greater than the first pressure of the fluid in the flow channel as is required by claim 1.

As *Richmond* does not describe each and every limitation of claim 1, claim 1 is allowable over *Richmond*.

C. 35 U.S.C. § 103(a) Rejection over *Blomquist* in view of *Brost*

Claims 1-3 are rejected under 35 U.S.C. § 103(a) as unpatentable over *Blomquist* in view of *Brost*.

As stated above, claim 1 requires a valve element that forms a first seal with the first valve seat in response to a first pressure, the first pressure resulting from fluid in the flow

channel, the valve element forming a second seal with the second valve seat in response to a second pressure, the second pressure resulting from fluid in the flow channel, the second pressure greater than the first pressure of the fluid in the flow channel, and the valve element forming an open configuration between said lumen and said flow channel in response to a third pressure resulting from fluid in the injection lumen the third pressure greater than one of said first pressure and said second pressure.

Appellee asserts that *Blomquist* describes all of the limitations of the claims except that it does not show “the flow lumen extending as claimed invention.” Office Action, page 4. The Appellee states that *Brost* discloses an injection port comprising a housing defining a flow channel 26 and an injection lumen 22 in communication with the flow channel. Office Action, page 5. Appellee states that it would have been obvious to modify *Blomquist* with a flow lumen or injection lumen extending as taught by *Brost*.

Lack of all Limitations

Appellant respectfully disagrees that *Blomquist* describes the limitations of claim 1 set forth above. *Blomquist* describes a bi-directional vent for a fuel tank that includes a seal element 37 that includes valve seats 38 and 39. Abstract and Figure 7. Instead of responding to pressures to cause the valve element to form seals against valve seats, *Blomquist* does the opposite. When the pressures inside the tank and outside the tank are equal, the valve element of *Blomquist* rests against the valve seats 38 and 39. Figure 7. When there is a pressure differential between the inside of the tank and the outside of the tank, the valve element either moves off of seat 39 to allow air to enter the tank, Figure 8, or off of seat 38 to allow air to exit the tank, Figure 9.

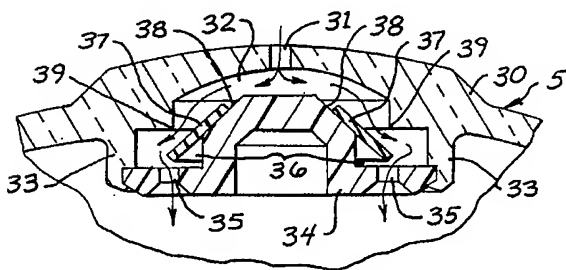


Figure 8 of *Blomquist*

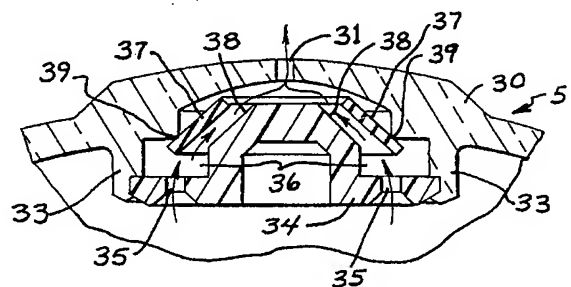


Figure 9 of *Blomquist*

Blomquist never responds to a first pressure by forming a first seal with the valve element disposed against a first valve seat.

Further, *Blomquist* never describes a first and a second pressure both resulting from fluid in a flow channel. Nor does *Blomquist* describe the valve element forming a second seal with the second valve seat in response to a second pressure, the second pressure resulting from fluid in the flow channel, the second pressure greater than the first pressure of the fluid in the flow channel as is required by claim 1. As *Blomquist* does not describe, and *Brost* is not relied upon as describing, a first pressure and a second pressure both resulting from fluid in a fluid channel where the second pressure is greater than the first pressure. Neither *Blomquist* nor *Brost*, alone or in combination, describe each and every limitation of claim 1 as required under 35 U.S.C. § 103.

Lack of Motivation to Combine

The Appellee has stated that it would be obvious to one skilled in the art to combine the pressure equalization valve of *Blomquist* into the lumen assembly of *Brost* “to provide the fluid communication with the other device.” Office Action, page 5. Appellant respectfully disagrees with the Appellee’s stated motivation and with the perceived result of such combination.

It is well settled that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 249 (CCPA 1959). *Brost* is a check valve assembly. Abstract. *Blomquist*, on the other hand, is a vent assembly to equalize differentials in pressure between the atmosphere and a fuel tank. Abstract. It is unclear to the Appellant how the Appellee intended to combine the two references, and further, what the functional result of such a combination might be. *Brost* is a check valve assembly whose operation is to allow fluid flow in one direction, but prevent fluid flow in the opposite direction. *Blomquist*, conversely, freely permits the flow of gasses in either direction to equalize pressure on both sides of the vent.

As the Appellee's combination would render one or the other reference unsuitable for its intended purpose, the motivation suggested by the Appellee is improper.

Claims 2 and 3 depend from claim 1 and inherit all of the limitations thereof. Claims 2 and 3, therefore, are patentable for at least the reasons set forth with respect to claim 1.

D. Nonstatutory Double Patenting

Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 5-7 of the '*861 patent*.

In the response dated August 28, 2008, Appellant pointed out that claims 1-3 require the valve element forming an open configuration between said lumen and said flow channel in response to a third pressure resulting from fluid in the injection lumen the third pressure greater than one of said first pressure and said second pressure. As this limitation is not found in claims 1-25 of the '*861 patent*, the claims of the present application are structurally distinguishable and therefore patentably distinct from the claims of the '*861 patent*. Appellant, therefore requests that the double patenting rejection be reversed.

Should the double patenting rejection be upheld by the Board, Appellant respectfully submits that he would be willing to file a terminal disclaimer to overcome the double patenting rejection.

VIII. CLAIMS APPENDIX

A copy of the claims involved in the present appeal is attached hereto as the Claims Appendix.

IX. EVIDENCE APPENDIX

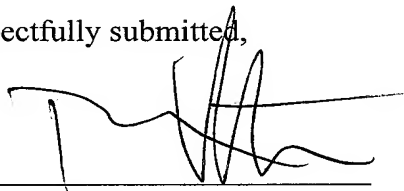
No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the examiner is being submitted.

X. RELATED PROCEEDINGS APPENDIX

No related proceedings are referenced in II above, hence copies of decisions in related proceedings are not provided.

Dated: February 19, 2010

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'Thomas Kelton', written over a horizontal line.

By
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CLAIMS APPENDIX

1. An injection port adapted for use with an intravenous line, comprising:
 - a housing defining a flow channel and having an injection lumen extending in fluid communication with the flow channel;
 - first portions of the housing defining a first valve seat around the injection lumen;
 - second portions of the housing defining a second valve seat around the injection lumen;
 - a valve element disposed to extend transverse to the injection lumen;
 - the valve element forming a first seal with the first valve seat in response to a first pressure, the first pressure resulting from fluid in the flow channel;
 - the valve element forming a second seal with the second valve seat in response to a second pressure, the second pressure resulting from fluid in the flow channel, the second pressure greater than the first pressure of the fluid in the flow channel, and
 - the valve element forming an open configuration between said lumen and said flow channel in response to a third pressure resulting from fluid in the injection lumen in said lumen the third pressure greater than one of said first pressure and said second pressure.
2. The injection port recited in claim 1, further comprising:
 - third portions of the housing defining a third valve seat on the side of the valve element opposite the first and second valve seats; and
 - the valve element having properties for forming a third seal with the third valve seat.
3. The injection port recited in claim 2, wherein the valve element has properties for opening at least the first seal for said open configuration under the pressure of an injectate in the injection lumen to create a flow path around the valve element between the injection lumen and the flow channel; and
 - the valve element has properties for opening the third seal in response to a partial vacuum in the injection lumen to aspirate a portion of the fluid in the flow channel through an aperture in the valve element and into the injection lumen.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.